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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

71375-0001.20

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on January 9, 2009 via EFS

Signature Karen Marcus

Typed or printed name Karen L. Marcus

Application Number

10/772,781

Filed

02/04/2004

First Named Inventor

Jerry B. Gin

Art Unit

1612

Examiner

Lezah W. Roberts

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 53,393

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

James S. Nolan
Signature

James S. Nolan

Typed or printed name

858-314-1500

Telephone number

January 9, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Jerry B. Gin
SERIAL NUMBER: 10/772,781 EXAMINER: Lezah Roberts
FILING DATE: February 4, 2004 ART UNIT: 1612
FOR: Long-Lasting, Flavored Dosage Forms For Sustained Release of Beneficial Agents within the Mouth

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Status of Claims

Claims 1-8, 12, 13, 23-26, 28, 29, 46-48, 55-57, 72-74, and 100 are currently pending. The Final Rejection sets forth the following rejections:

- Claim 100 remains rejected under 35 U.S.C. § 112, first paragraph, as allegedly adding new matter.
- Claims 9 and 100 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.
- Claims 1-8, 12, 13, 23-25, 30, 46-48, 72, 73, and 100 remain rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over Alderman et al. (US Patent No. 4,528,125).
- Claims 26, 28, 29, and 55-57 remain rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over Alderman in view of Ventouras (US Patent No. 6,183,775).
- Claims 1-8, 12, 13, 23-26, 28, 29, 46-48, 55-57, and 72-74 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over Applicants' co-pending application Serial No. 11/904,420, which rejection has been held in abeyance.

In an Advisory Action responding to Applicants' response to the foregoing, the Examiner declined to withdraw the rejections of the claims.

The Applicants' replies to the above rejections were presented in the response mailed November 10, 2008, and are herein incorporated by reference. Briefly, with respect to the § 112 rejections of Claims 9 and 100, the Applicants contend that the term "substantially," as recited in the claims, does not constitute new matter, nor does it render the claims indefinite. See paragraph 31 of the published application, which states that in some embodiments, the recited wet matrix of the lozenge gradually releases the flavoring agent but does not otherwise dissolve in the mouth. The Applicants contend, therefore, that there is support within the specification for a lozenge that does not substantially dissolve in the mouth. Further, according to M.P.E.P. § 2173.05(b)(D) the term "substantially" has been held to be definite. Accordingly, in view of the above, the recitation of the term "substantially," as recited in the claims, is fully supported by the specification, and in view of M.P.E.P. § 2173.05(b)(D), the term "substantially" does not

render the claims indefinite. The Applicants therefore respectfully request that this rejection be withdrawn.

With respect to the 35 U.S.C. § 103 (a) rejections of claims 1-8, 12, 13, 23-25, 26, 28-30, 46-48, 55-57, 72-73 and 100, both rejections rely, at least in part, on Alderman. The Applicants respectfully traverse. Alderman does not teach or suggest a "wet matrix," as that term is defined and used within the context of the Applicants' specification, and, in fact, Alderman teaches away from a matrix composition. Accordingly, the Office has not established a *prima facie* case of obviousness because Alderman does not teach or suggest all the elements of the rejected claims and in fact teaches away from the claimed invention in contravention of M.P.E.P. § 2145. Therefore, as explained in further detail below, these rejections are based on errors in fact. As such, the Office's *prima facie* case of obviousness is deficient and these rejections should be withdrawn.

The reliance of the Office upon Alderman as allegedly teaching a "wet matrix" is in error for several reasons. First, instead of giving weight to the Applicants' definition of a "wet matrix," as set forth at paragraph 44 of the published application, the Office relies upon the Merriam Webster dictionary for a general definition of the term "matrix," and then erroneously asserts that Alderman teaches such a matrix. According to M.P.E.P. § 2173.05(a) an applicant is entitled to be his own lexicographer. In this instance, the Applicants have defined a "wet matrix" as the product that results from admixing an essential oil with a polymeric material (e.g., ethyl cellulose particles) in a ratio that ensures formation of a matrix having a wet, sticky surface and/or a rubbery, soft consistency. See, e.g., paragraph 44. The Applicants further characterize this interaction at paragraph 38 wherein it is stated that the wet matrix forms because the polymer slightly dissolves in the essential oil. Accordingly, as is clear from the context of the Applicants' disclosure, what is meant by a "wet matrix" is the product that results from mixing a sufficient amount of essential oil with a sufficient amount of polymer particles, with the essential oil slightly dissolving the surface of the polymer particles to create a sticky surface that then provides the "glue" that holds the particles together to form the "wet matrix." The term "wet" is not used to connote an interaction with water, but is rather referring to the surface dynamics that result from the intermolecular interaction between the essential oil and the surface of the polymer particles. This is completely different from the composition disclosed in Alderman.

Alderman discloses dispersion. The dispersion includes a plurality of finely divided individual cellulose ether particles that have been dispersed in a large quantity of an aqueous phase (e.g., water). The dispersion also includes a fragrance or flavor that reversibly diffuses into the individual cellulose particles. This is clearly seen at column 2, lines 52-53 of Alderman. Hence, the cellulose particles in Alderman remain as individual particles with a fragrance or flavor diffused therein. Alderman is specifically directed to a method for making a particulate composition using a process that involves: (1) preparing an aqueous dispersion of (a) polymer, (b) fragrance or flavor, and (c) a suspending agent that facilitates dispersion; (2) heating the dispersion to facilitate diffusion of the fragrance or flavor from the aqueous vehicle into the polymer particles;

and in certain instances (3) spraying, dewatering, or otherwise forming a dry final product from the mixture. See column 6, lines 1-53. In viewing the reference in the light most favorable to the position of the Office, it can be seen that the reference at most discloses a dewatered composition containing polymer particles with flavor incorporated therein. It is this inferred composition that the Examiner contends is equivalent to the Applicants' claimed "wet matrix."

However, as can be seen with respect to the above, Alderman's dewatered composition is not a "wet matrix" as that term is defined and used in Applicants' specification. In fact, at column 1, lines 36 to 45, Alderman actually teaches away from a matrix composition, citing deficiencies inherent in such systems; further, at column 6, lines 30-39, Alderman teaches that the disclosed dispersions are advantageous over those systems that employ a matrix.

The Applicants' claimed sustained release wet matrix is meaningfully distinguishable from and nonobvious over the composition described by Alderman. As explained in the Applicants' specification, in the section "Methods of Manufacture and Use," the Applicants' wet matrix is prepared by simple admixture of the particulate polymer, e.g., ethyl cellulose, and the essential oil component, at room temperature; this mixture is allowed to set and may then be shaped to form a lozenge. The composition is not aqueous, liquid is not removed, and the essential oil component coats the polymer particles rather than diffusing into them. Therefore, the resulting wet matrix claimed by the Applicants, as explained in the Applicants' specification, is composed of a fairly soft and rubbery and/or discernibly wetted or sticky substance.

The polymer particles of the Applicants' claimed lozenge release a flavor over a time period in the range of 15 or so minutes to several hours. By contrast, Alderman's product, because it is necessarily far more dense and dry, very slowly releases fragrance or flavor that has diffused into the interior of the particles. See Alderman's examples, where it is explained that the fragrance or flavor still remains after 3-6 days (3 days in Example 2, 6 days in Example 1), a time period that would obviously be unsuitable for a lozenge as claimed by applicants. The reason Alderman uses the aqueous dispersion, as explained throughout the patent, is to ensure that the fragrance actually diffuses into the polymer particles rather than merely coating the particle surface, as is the case in applicants' wet matrix. This means that the dewatered, dried composition of Alderman will be very dense as well as essentially dry (even if higher levels of flavor are used, since liquid is removed), thereby giving rise to the approximately week-long sustained release profile described in the examples, a profile that might be appropriate for a fragrance-releasing product but which, as noted above, would be unacceptable for sustained release lozenges.

Accordingly, the Applicants' claims specify a "wet matrix" that is composed of ethylcellulose and a flavoring agent, whereas Alderman's dense, dried composition would necessarily be composed of individual polymer particles that contain a fragrance agent internally. Thus, Alderman does not teach or suggest a "wet matrix," as claimed by the

Applicants. This distinction on the molecular level gives rise to significant differences macroscopically, i.e., with respect to the chemical composition, physical properties, and function of the final product. As Ventouras was cited solely for its disclosure of a sweetener, that secondary reference fails to remedy the deficiencies of Alderman.

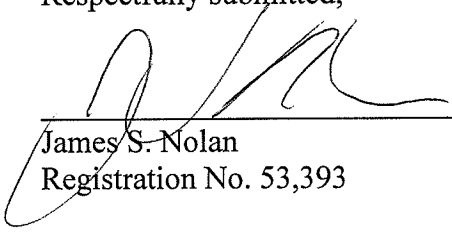
Therefore, in view of the above, the Office has not established a *prima facie* case of obviousness because Alderman and/or Ventouras, alone or in combination, does not teach or suggest all the elements of the rejected claims, as required by M.P.E.P. § 2143, and in fact Alderman teaches away from the claimed invention in contravention of M.P.E.P. § 2145. Therefore, since a *prima facie* case of obvious has not been established these rejections should be withdrawn.

CONCLUSION

An indication of allowance of all claims is respectfully requested. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicant would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

It is believed that no additional fees are required with this submission. However, in the event that additional fees are deemed necessary, or in the event of any variance between the amount enclosed and the fees determined by the USPTO, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0311, Reference No. 71375-0001.20

Respectfully submitted,



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Date: January 9, 2009

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